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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,633	07/29/2003	Armin Breitenbach	6102-000068/US	9056
28997 7590 03/19/2009 HARNESS, DICKEY, & PIERCE, P.L.C 7700 Bonhomme, Suite 400 ST. LOUIS, MO 63105			EXAMINER TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/630,633	Applicant(s) BREITENBACH ET AL.	
	Examiner S. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18 and 20-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18 and 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16, 18 and 20-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-59 of copending Application No. 10/523908 ('908). Although the conflicting claims are not identical, they are not patentably distinct from each other because application '908 claimed a transdermal therapeutic system (TTS) comprising a drug-containing hot-melt adhesive matrix produced by metering the drug into the solvent-free melt of the adhesive matrix at a temperature of 102°C-160°C. The TTS further comprises a drug and a softener (claims 28 and 31). Hot-melt adhesive includes amine-resistant silicone (claim 31). Softeners are found in claims 32 and 33. Drug include Rotigotine is found in

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claims 28, 29 and 42-44. Amount of drug is found in claims 34-36. Drug present in form of a base is found in claim 37. Release profile is found in claims 46-48.

Accordingly, the present claims are anticipated by the claims of the '908 application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The 112 rejections have been withdrawn in view of applicant's Remarks filed 12/22/08.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-16, 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Metman et al. (Clinical Neuropharmacology) and Loper et al. US 4,880,633.

Chen teaches a TTS comprising a backing layer, and an adhesive polymeric matrix which contains combination of a permeation enhancer and at least about 30% ropinirole or an analog thereof as an active agent (abstract; column 3, lines 1-37; column 4, lines 25-37; and column 6, lines 36-46). Permeation enhancer includes

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polyethylene glycol, propylene glycol, alcohol, and the like (column 7, lines 24-39).

Active agent can be administered in the form of a base or pharmaceutically acceptable salt (column 7, lines 6-10). The polymeric matrix further comprises pressure sensitive adhesive polymer including silicone (column 8, lines 48-67).

Chen does not expressly teach the claimed active agent.

Metman teaches transdermally administering rotigotine for the treatment of Parkinson's disease (abstract). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen to include rotigotine as an active agent in view of the teaching of Metman, because Metman teaches that rotigotine is an effective treatment for advanced Parkinson's disease with mild adverse effects compare to other active agent, because Metman teaches using rotigotine for the treatment of Parkinson's disease allows patients to substantially lower L-Dopa doses without loss of antiparkinsonian efficacy, and because Chen teaches the desirability to obtain a TTS useful for the treatment of Parkinson's disease.

Chen is silent with respect to the teaching of hot-melt process.

Loper teaches a transdermal drug delivery system comprising a drug reservoir matrix. The drug reservoir matrix is coated onto the backing layer using hot melt deposition process (column 8, lines 18-36). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen using the hot-melt deposition process of Loper to obtain the claimed invention. This is because Loper teaches hot melt process is well known in the art, because Loper teaches using hot melt process as an alternative process to deposit the drug reservoir matrix onto the backing layer, and

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because Chen teaches the desirability for obtaining a TTS having a drug reservoir matrix.

Claims 1-16, 18 and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. US 5,807,570, in view of Metman et al. (Clinical Neuropharmacology) and Loper et al. and Noel. US Re. 36,754

Chen is relied upon for the reason stated above. Chen further does not teach the matrix system that comprises organic wax.

Noel teaches a hot-melt silicone-base TTS comprising silicone sensitive adhesive, and organic waxes having melting point between 30-150°C (abstract). Organic waxes include vegetable waxes, animal waxes, mineral waxes such as ozokerite, and mixtures thereof in an amount of from about 1 to about 25% (column 5, lines 1-11; and claim 17). Silicone sensitive adhesive is present in an amount from about 99-85% (column 8, lines 41-44). Noel further teaches the hot-melt silicone-base TTS is free of solvent (column 2, lines 66-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the TTS of Chen using the hot-melt silicone-base TTS in view of the teaching of Noel to obtain the claimed invention. This is because Noel teaches a transdermal system that is highly efficacious, because Noel teaches using organic waxes to decrease viscosity and improve coatability which do not require the present of solvents (column 1, lines 66 through column 2, lines 1-3), because Noel teaches using organic waxes over the use of solvents to avoid: 1) removal and containment of solvents, 2) special precautions to avoid fires, and 3) cost effectiveness

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(ID), because Chen teaches a TTS that comprises silicone and waxes as carriers (column 6, lines 25-27), and because Chen teaches the desirability to obtain a TTS that improved patient compliance and with less side effects (column 2, lines 51-60).

Response to Arguments

Applicant's arguments filed 12/22/08 have been fully considered but they are not persuasive.

Applicant states that Applicant may elect to argue to overcome the provisional obviousness-type double patenting rejection or to provide a terminal disclaimer (to the extent necessary) once the present claims have been found to be otherwise allowable and/or once the co-pending application issues as a patent.

Accordingly, the rejection is maintained.

Applicant argues that Chen does not teach the active agent is dispersed and melted.

However, in response to applicant's argument, it is noted that the rejection claims are directed to a product claims. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir.

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1985). With respect to the method claims, it is noted that the claims do not require melting the active agent.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615